I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company BIAL-Portela & C[a], S.A. submitted in 2021 an application for Misofar 25 micrograms vaginal tablets[1] (RH099) to be assessed with the aim of including Misofar 25 micrograms vaginal tablets in the list of prequalified medicinal products for the treatment of reproductive health conditions in women.

Misofar 25 micrograms vaginal tablets was assessed according to the '*Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies*' by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

2. Steps taken in the evaluation of the product

November 2021	During the meeting of the assessment team the quality data were reviewed and further information was requested.
November 2021	The company's response letter was received.
November 2021	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2021	The company's response letter was received
November 2021	The quality data were reviewed and found to comply with the relevant WHO requirements.
16 December 2021	Misofar 25 micrograms vaginal tablets was included in the list of prequalified medicinal products.

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified-lists

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility Throughout this WHOPAR the proprietary name is given as an example only